

**REMARKS**

Claims 1-50 were pending and were rejected under 35 U.S.C. § 103. In view of the foregoing amendments, claims 1-4, 8-10 and 12-50 are pending as shown above. In particular, Claim 1 has been amended to make explicit that the x-ray image includes an image of bone, as described throughout the specification as filed and in original claims 5 and 8. Claims 8 and 12 have been amended to correct dependencies in view of the amendment to claim 1. No new matter has been added as a result of these amendments, which are made solely to expedite prosecution, and entry thereof is respectfully requested. In view of the following remarks, Applicant submits that pending claims 1-4, 8-10, and 12-50 are in condition for allowance.

**Rejections Under 35 U.S.C. § 103(a)**

**A. Claims 1-5, 13-31 and 48 over Inga in view of Fishman**

Claims 1-5, 13-31 and 48 stand rejected as allegedly obvious over U.S. Patent No. 5,384,643 (hereinafter "Inga") in view of U.S. Patent No. 5,271,401 (hereinafter "Fishman"). (Office Action, paragraphs 3-24). The Office Action states that it would have been obvious to modify the methods of digitizing and transmitting x-ray images described in Inga with the methods of deriving quantitative information from x-ray images described in Fishman to arrive at the subject matter of claims 1-5, 13-31 and 48.

Claim 1 has been amended to make explicit that the quantitative information derived is information regarding bone. (See, also, original claims 5 and 8). Fishman's methods relate entirely to radiological imaging of gas spaces and in no way suggest that the image include bone as claimed by Applicants. See, col. 6, lines 20-28 and claims of Fishman. Accordingly, there is no combination of Inga and Fishman that renders pending claims 1-5, 13-31 and 48 obvious and withdrawal of the rejection is respectfully requested.

**B. Claims 6-12 over Inga in view of Arnold**

Claims 6-12 stand rejected as allegedly obvious over Inga in view of U.S. Patent No. 5,335,260 (hereinafter "Arnold"). (Office Action, paragraphs 25-31). The Office Action states that it would have been obvious to "further modify the method of Inga such that it incorporated an x-ray image including an external standard. One would have been motivated to make such a

modification so that x-ray imagery could be quantified for calcium, bone mass and bone density by comparison of x-ray attenuation caused by an external standard to the attenuation caused by the object of interest as taught in Arnold [citation omitted]." (Office Action, paragraph 29).

Claims 6 and 7, directed to methods in which an external standard such as a calibration phantom, are used have been canceled, without prejudice or disclaimer to their reintroduction in a continuation applications. Further, with regard to claims 8-12, the Office readily admits that Arnold requires the use of a calibration phantom and, accordingly, is not relevant to these claims. Accordingly, to the extent that this rejection is not obviated by cancellation of claims 6 and 7, Applicants respectfully submit that the rejection is improper and should be withdrawn.

C. Claims 32-45 and 47 over Chiabrera

Claims 32-45 and 47 stand rejected as allegedly obvious U.S. Patent No. 5,917,877 (hereinafter "Chiabrera"). (Office Action, paragraphs 32-46). The Office Action asserts that it would have been obvious from Chiabrera to place the calibration phantom in a position of known density. (Office Action, paragraph 36). In addition, it is alleged that this reference suggests "a method of providing an assembly according to claim 32, wherein the calibration phantom is positioned such that x-rays pass through a subject and the calibration phantom simultaneously, wherein the calibration phantom projects free of materials that alter its apparent density (see Fig. 2 above); creating an image of the phantom and the portion of the subject's anatomy; comparing the image of the phantom and the subject's anatomy to determine bone mineral density of the subject (abstract; columns 1-3, column 4, lines 1-41)." (Office Action, paragraph 46).

Applicants traverse the rejection for the reasons of record, reiterated herein. (See, *e.g.*, pages 5-7 of Response filed April 4, 2003).

Chiabrera does not suggest that a calibration phantom should be placed in an area of known density. Indeed, Chiabrera is completely silent in this regard, focusing entirely on the materials making up the calibration phantom. This reference, like the art as a whole, assumes that placement alongside the bone is sufficient to ensure accuracy and provides no motivation or suggestion to move the calibration phantom such that it projects in an area of known density. See, *e.g.*, Chiabrera, col. 6, lines 41-44 and claims. Teaching that calibration phantoms can be useful is a far cry from recognizing or suggesting that tissues projecting with the calibration phantom could affect its apparent density, as disclosed and claimed by Applicants. See, *e.g.*,

page 31, lines 14-27 of the application. Simply put, there is nothing in Chiabrera, or the art as a whole, that would have reasonably lead the skilled artisan to the claimed assemblies. Therefore, withdrawal of this rejection is respectfully requested.

D. Claim 46 over Chiabrera in view of Inga

Claim 46 stands rejected as allegedly obvious over Chiabrera in view of Inga. (Office Action, paragraphs 47-50). The Office Action alleges that "it would have been obvious to modify the method of Chiabrera such that it incorporated the step of comparing performed in a network environment ... so that the analysis could be accentuated by the ability of access several image and patient data from an archive source as taught by Inga." (Office Action, paragraph 50).

Claim 46 depends ultimately from claim 32. As such, the method of claim 46 requires the use of an assembly in which the calibration phantom is positioned in an area of known density. For the reasons of record and those detailed above in section C, both the art as a whole and Chiabrera in particular fail to teach or suggest placement of a calibration phantom in any area of known density. Accordingly, there is no combination of Chiabrera and Inga that would reasonably lead one of skill in the art to the method of claim 46.

E. Claims 49 and 50 over Chiabrera in view of Barnhill

Claims 49 and 50 stand rejected as allegedly obvious over Chiabrera in view of U.S. Patent No. 6,248,063 (hereinafter "Barnhill"). (Office Action, paragraphs 51-54). The Office Action maintains that it would have been obvious to modify that method of Chiabrera such that is comprised administering a suitable treatment in view of Barnhill's teachings. (Office Action, paragraph 54).

Claims 49 and 50 depend ultimately from 1. Accordingly, these claims necessarily involve transmission of digitized x-ray images and analysis of these images. Chiabrera is completely silent as to transmitting a digitized x-ray image to a remote computer, as required by claims 49 and 50. For its part, Barnhill also fails to suggest transmission of x-ray images. As previously set forth in detail in the Response mailed April 4, 2003, Applicants again note that Barnhill refers only to transmission of digitized biomarker or demographic data values. (col. 7, line 49; col. 12, lines 52-67; col. 16, lines 57-65; col. 24, line 58-65 and Examples of Barnhill). Barnhill clearly does not consider x-ray images to be patient data as x-rays are mentioned only in

relation to “mechanistic modeling” (col. 20), namely comparison of digitized biomarker values with **known** information about particular diseases gathered from known diagnostic methods such as x-rays. *See, also*, col. 20, lines 3-10).

In sum, there is nothing in Chiabrera or Barnhill that relates to the providing, transmitting and/or analysis of a digitized x-ray image itself. Therefore, Applicant respectfully requests that this rejection be withdrawn.

**CONCLUSION**

Applicant submits that the claims are in condition for allowance and request early notification to that effect. If the Examiner has any further issues or wishes to discuss any of the foregoing, she is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

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